REMARKS

In the Office Action dated February 6, 2003, claims 29-38 are pending and are under consideration. Claims 31-33 are rejected under 25 U.S.C. §112, first paragraph, as allegedly not supported by an enabling disclosure. Claims 29-38 are rejected under 35 U.S.C. §112, first paragraph, for allegedly lacking enabling support. Claims 29-32 and 34-38 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Conrad et al. (WO 95/25541 or "Conrad et al."). Claims 29-32 and 34-38 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent 5,889,166 to Conrad et al. ("the '166 patent").

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Regarding the rejection of claims 31-33 under 25 U.S.C. §112, first paragraph, the Examiner contends that, because these claims specifically recite *N. caninum* strain NC-1, a suitable deposit of this strain is required. The Examiner states that the specification lacks complete deposit information for the deposit of *N. caninum* strain NC-1. The Examiner further states that if the deposit has been made, filing of a declaration by Applicant or the Assignee or a statement by an attorney of record is required in compliance with the provisions of the Budapest Treaty. In addition, the Examiner states that the deposited biological material must be viable at the time of the deposit and during the term of deposit.

In response, Applicants respectfully submit that the NC-1 strain, available by way of infected MARC 145 cells, has been deposited with the American Type Culture Collection (ATCC) and has been assigned the ATCC designation No. CRL-12231. Applicants have amended the specification to include the date of the deposit and the current address of the

ATCC. A copy of the deposit certification from the ATCC, which includes a statement of viability, is attached hereto.

Applicants further submit that all restrictions on availability of such deposited strain to the public will be irrevocably removed upon the granting of the patent based upon the captioned application and said strain will remain permanently available for a term of at least 5 years after the most recent request for the furnishing of a sample, and in any case, for a period of at least 30 years after the date of deposit or for the enforceable life of the U.S. patent whichever is longer. In the event that the strain becomes non-viable or is inadvertently destroyed, such will be replaced with a viable strain of the same taxonomic description.

As such, Applicants respectfully submit that the rejection of claims 31-33 under 35 U.S.C.§112, first paragraph, as it relates to the deposit requirements, is overcome. Withdrawal of the rejection is therefore respectfully requested.

Turning to the rejection of claims 29-38 under 35 U.S.C. §112, first paragraph, the Examiner alleges that the prior art teaches that it is unpredictable to treat or prevent neosporosis in mammals. The Examiner states that the prior art specifically teaches that homogenates prepared from cells of *Neospora* can be used to induce neosporosis in mammals. The Examiner has cited Barr et al. (*J. Vet Diagnosis.* 6(2): 7308 (1993)), Lindsay et al. (*Am. J. Vet Res.* 56(9): 1176-1180 (1995)) and Lindsay et al. (*J. Parasitol.* 76(3): 410-413 (1990)) as support for her position. The Examiner is of the opinion that the homogenate recited and employed in the instantly claimed methods does not distinguish over the homogenates used in the references. Notably, the cited references actually teach induction and not protection against, neosporosis.

The Examiner contends that preparing homogenates from *Neospora* tachyzoites and/or cells infected with *Neospora* tachyzoites, as described in Example 1 at page 15, lines 10-29 of the specification, resulted in a unique *Neospora* antigen (NSA) preparation that did not contain any viable tachyzoites. The Examiner recognizes that Applicants have demonstrated that the use of this preparation conferred immune protection in mammals challenged with N. *caninum*. However, the Examiner contends that the specification does not teach that any other homogenate, antigen or preparation can protect mammals against neosporosis. The Examiner suggests that the claims be amended to incorporate the distinguishing characteristics of Applicants' homogenate.

In response, Applicants respectfully submit that the term "homogenate", as presently recited in the claimed methods, is defined in the specification at page 9, lines 12-13, as a preparation obtained by homogenizing or disrupting whole cells of *Neospora*. A homogenate of *Neospora* in the context of the present invention is clearly not a homogenate of host cells infected with *Neospora*. In contrast, the references cited by the Examiner, i.e., Barr et al. (1993), Lindsay et al. (1995) and Lindsay et al. (1990), merely disclose the preparation of live tachyzoites by disrupting infected host cells, and the use of these tachyzoites for inducing neosporosis in a mammal. None of the cited references teach the preparation of a homogenate of *Neospora* and the use of a *Neospora* homogenate for inducing protective immunity in a mammal against neosporasis.

The specification demonstrates in Example 1, at page 14, line 28 to page 15, line 29 that a homogenate of *Neospora* is prepared by first preparing free tachyzoites from an infected host cell culture and then disrupting the free (and viable) tachyzoites. A homogenate of tachyzoites made by disrupting the tachyzoites certainly should not, and did not, contain any

viable tachyzoites. Furthermore, Applicants submit that the present specification provides a clear showing of the ability of homogenates prepared from *Neospora* cells to induce protective immunity in mammals. For example, see pages 16-20, Examples 2-3 of the present specification.

Applicants further respectfully submit that Example 1 of the specification is merely an exemplification of how a homogenate of *Neospora* can be prepared. Applicants should not be required to limit the claims only to the use of a homogenate of *Neospora* as prepared in Example 1. As stated in the specification, at page 9, lines 1-11, the homogenate can be made using various types of *Neospora* cells and a variety of homogenization methods. In light of the present teaching, those skilled in the art would be able to make and use homogenates of *Neospora* to induce protective immunity in a mammal against neosporosis, as presently claimed.

Accordingly, it is respectfully submitted that the claimed methods are fully supported by an enabling disclosure. The rejection of claims 29-38 under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

With respect to the rejection of claims 29-32 and 34-38 under 35 U.S.C. §102(b) as allegedly anticipated by Conrad et al. (WO95/25441), the Examiner alleges that Conrad et al. teach a homogenate prepared from a culture of biologically pure, isolated bovine *Neospora* tachyzoites. The Examiner refers to the abstract, page 4, lines 1-13; page 8, lines 5-15; page 23, lines 20-22; page 38, line 34; page 39, line 5 and especially page 39, lines 15-30, of Conrad et al., for such alleged teaching. Relying on page 33, lines 23-30, the Examiner also alleges that the homogenate prepared from a crude extract of isolated bovine *Neospora* tachyzoites BPA1 and BPA2 has equivalent antigenic components to the homogenate prepared from

Neospora caninum NC-1 tachyzoites. Additionally, the Examiner alleges that Conrad et al. specifically teach, at page 53, lines 17-20, administering to a mammal an effective amount of the *Neospora* vaccine in order to treat or prevent an infection caused by *Neospora*. The Examiner contends that the *Neospora* preparation disclosed by Conrad et al. clearly meets Applicants' definition of a homogenate. Therefore, the Examiner concludes that Conrad et al. anticipates the claimed methods of protecting a mammal against neosporosis by using a homogenate of *Neospora*.

In response, Applicants respectfully submit that Conrad et al. do not teach the preparation of a homogenate of *Neospora* as defined in the present specification. As submitted above, the term "homogenate", as recited in the claimed methods, is defined in the specification at page 9, lines 12-13, as a preparation obtained by homogenizing or disrupting whole cells of *Neospora*, not host cells infected with *Neospora*. The disclosure of Conrad et al. at page 4, lines 1-13; page 8, lines 5-15; page 38, line 34; page 39, lines 5 and 15-30, which is relied upon by the Examiner, relates to the preparation of live, viable tachyzoites of *Neospora*, not a homogenate obtained by homogenizing or disrupting *Neospora*.

As to page 33, lines 23-30 of Conrad et al., this portion of Conrad et al. merely comments on the reactivity of *in vitro* cultivated tachyzoites, i.e., live *Neospora* isolates, with rabbit polyclonal antisera. There is no teaching of a homogenate prepared from *Neospora* isolates or the antigenic components of such homogenate. Thus, the Examiner's statement that the homogenate prepared from a crude extract of isolated bovine *Neospora* tachyzoites BPA1 and BPA2 has equivalent antigenic components to the homogenate prepared from *Neospora caninum* NC-1 tachyzoites, is unfounded.

As to page 23, lines 20-25 of Conrad et al., it is stated that a vaccine may comprise a crude extract of *Neospora* tachyzoites, bradyzoites or other stages, or comprise partially or completely purified *Neospora* protein preparations. However, Conrad et al. provide no teaching, much less an enabling teaching, as to how "a crude extract" can be prepared that would have the capacity of inducing protective immunity in a mammal against neosporosis. For anticipation, a prior art must place the invention in possession of the public by providing an enabling disclosure of the claimed subject matter. Scripps Clinic & Research Foundation v. Genetech, Inc., 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), certi. denied, 112 S. Ct. 169 (1991). In fact, Conrad et al. used live, infectious *Neospora* tachyzoites to infect cattle, attempting to induce immunity in the infected cattle. Applicants submit that those skilled in the art would not consider using infectious, unattenuated *Neospora* tachyzoites as a vaccine for administration to cattles.

In contrast, the presently claimed methods employ a homogenate of *Neospora*, i.e., a homogenate made by disrupting *Neospora* cells. The present specification provides detailed teaching as to how a homogenate can be prepared from *Neospora* cells, e.g., at page 14-15 (Example 1), and how such a homogenate induced protective immunity in mammals, e.g., at pages 16-20 (Examples 2-3).

Accordingly, Applicants respectfully submit that Conrad et al. do not teach the claimed methods. The rejection of claims 29-32 and 34-38 under 35 U.S.C. §102(b) as allegedly anticipated by Conrad et al. is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 29-32 and 34-38 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent 5,889,166 to Conrad et al. ("the '166 patent").

The Examiner alleges that the '166 patent teaches pharmaceutical compositions for the treatment and prevention of *Neospora* infections. According to the Examiner, the '166 patent discloses that *Neospora* vaccines may comprise a crude extract of *Neospora* tachyzoites (column 12, lines 51-52). The Examiner also alleges that the homogenate prepared from a crude extract of isolated bovine *Neospora* tachyzoites BPA1 and BPA2 has equivalent antigenic components to the homogenate prepared from *Neospora caninum* NC-1 tachyzoites. Additionally, the Examiner alleges that the '166 patent specifically discloses that "cows infected using culture-derived tachyzoites mount a protective immune response and prevent transplacental infection of the fetus" (col. 11, lines 60-65 and col. 28, lines 1-4).

Applicants respectfully submit that the Examiner's statement that the homogenate prepared from a crude extract of isolated bovine *Neospora* tachyzoites BPA1 and BPA2 has equivalent antigenic components to the homogenate prepared from *Neospora caninum* NC-1 tachyzoites is unfounded. Applicants submit that the '166 patent does not disclose a homogenate of *Neospora* tachyzoites, or how to prepare a homogenate of *Neospora* tachyzoites. The '166 patent merely discloses the reactivity of *in vitro* cultivated tachyzoites, i.e., live *Neospora* isolates, with rabbit polyclonal antisera.

Furthermore, Applicants respectfully submit that the protection of cows against *Neospora* infection, as disclosed at col. 11, lines 60-65 and col. 28, lines 1-4 of the '166 patent, was achieved with live, infectious, unattenuated tachyzoites. There is no teaching in the '166 patent that a homogenate of *Neospora* is capable of inducing a protective immune response in a mammal.

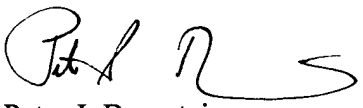
It is recognized that the '166 patent mentions at column 12, lines 51-52, that *Neospora* vaccines may comprise a crude extract of *Neospora* tachyzoites. However, Applicants submit that the '166 patent does not provide any teaching, much less an enabling teaching, as to how "a crude extract" can be prepared that would have the capacity of inducing protective immunity in a mammal against neosporosis. For anticipation, a prior art must place the invention in possession of the public by providing an enabling disclosure of the claimed subject matter. Scripps Clinic & Research Foundation v. Genetech, Inc., 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), cert denied, 112 S. Ct. 169 (1991).

Accordingly, Applicants respectfully submit that the '166 patent does not teach the claimed methods. The rejection of claims 29-32 and 34-38 under 35 U.S.C. §102(e) as allegedly anticipated by the '166 patent is overcome. Withdrawal of the rejection is therefore respectfully requested.

Finally, Applicants have added claims 52-54, which depend from claim 29, to delineate certain preferred features of the claimed invention. In claim 52, the homogenate is characterized as "free of viable cells of Neospora". Support for claim 52 is found in the specification, e.g., implicitly at page 9, lines 12-13, and explicitly at page 15, line 26. In claim 53, the homogenate is characterized as "a whole cell preparation". Support for claim 53 is found in the specification, e.g., at page 9, lines 13-15. In claim 54, the homogenate is characterized as "made by homogenizing or disrupting cells of *Neospora* by freeze-thawing, osmotic bursting, grinding, sonication, use of a polytron, blender, or tissue homogenizer". Support for claim 54 is found in the specification, e.g., at page 9, lines 7-11. No new matter is introduced by the foregoing amendments.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Peter I. Bernstein
Registration No. 43,497

Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, New York 11530
Telephone: 516-742-4343

PIB/XZ:ab

Enc.: ATCC Certification